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APPLICATION NO.	FILING DATE	FIRST NAMED	INVENTOR		ATTORNEY DOCKET NO.
09/016,737	01/30/98	MURPHY		G	8511-007
- - 020583 HM22/0928				EXAMINER	
PENNIE AND EDMONDS				EYLER	, Y
1155 AVENUE OF THE AMERICAS				ART UNIT	PAPER NUMBER
NEW YORK N	Y 10036-271	1		1642	9
				DATE MAILED:	09/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

# Office Action Summary

Application No. 09/016,737 Applicant(s)

Murphy et al.

Examiner

Yvonne Eyler

Group Art Unit 1642

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X Responsive to communication(s) filed on <u>Jul 8, 1999</u>	<u> </u>				
☐ This action is <b>FINAL</b> .					
☐ Since this application is in condition for allowance except for formal in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D.					
A shortened statutory period for response to this action is set to expir is longer, from the mailing date of this communication. Failure to respapplication to become abandoned. (35 U.S.C. § 133). Extensions of 37 CFR 1.136(a).	ond within the period for response will cause the				
Disposition of Claims					
	is/are pending in the application.				
Of the above, claim(s) 1-22, 25, and 27					
☐ Claim(s)	is/are allowed.				
X Claim(s) 23, 24, 26, and 28-30	is/are rejected.				
Claim(s)					
☐ Claims a					
Application Papers					
☑ See the attached Notice of Draftsperson's Patent Drawing Review  ■ Patent Drawing Review	ew, PTO-948.				
☐ The drawing(s) filed on is/are objected to t	by the Examiner.				
☐ The proposed drawing correction, filed on	is approved disapproved.				
☐ The specification is objected to by the Examiner.	•				
☐ The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. § 119					
☐ Acknowledgement is made of a claim for foreign priority under	35 U.S.C. § 119(a)-(d).				
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the particular in	riority documents have been				
received.					
received in Application No. (Series Code/Serial Number)	<u> </u>				
received in this national stage application from the Interna	ational Bureau (PCT Rule 17.2(a)).				
*Certified copies not received:					
☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).					
Attachment(s)					
☑ Notice of References Cited, PTO-892					
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s)	<u>5</u>				
☐ Interview Summary, PTO-413					
M Notice of Draftsperson's Patent Drawing Review, P10-948					
☐ Notice of Informal Patent Application, PTO-152	,				
SEE OFFICE ACTION ON THE FOLLOWING PAGES					

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### **DETAILED ACTION**

1. Applicant's election without traverse of Group III claims 23-30, species (a) antigens and sequences derived from prostate cell lysates in Paper No. 8 is acknowledged.

Claims 1-22, 25 and 27 are withdrawn from further consideration as being drawn to a nonelected invention.

Claims 23-24, 26, and 28-30 are under consideration. Claims 24 and 30 include nonelected species, but will be examined in light only of the elected species.

# Specification

The disclosure is objected to because of the following informalities: Page 7, lines 24 and 31 and page 8, lines 6 and 11 contain sequence disclosure without the corresponding SEQ ID NO. Also on page 7 is the recitation of Figure 9A-C, however, Figure 9 does not have a labeled A, B, or C section.

Appropriate correction is required.

# Claim Rejections - 35 USC § 112

2. Claims 23, 24, 26, and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 23 recites dendritic cells which "have been exposed" to antigen, which is vague and indefinite because the metes and bounds of the actions encompassed by the term "exposed" cannot be determined. It is not clear from the claim language if the "exposure" has any effect on the dendritic cells to render them distinct from normal isolated dendritic cells. One way to clarify this is to include that the exposure results in presentation of the antigen or results in DC's which have taken up the antigen.

Claims 24 and 30 recite the limitation "the prostate cancer patient" for which there is . insufficient antecedent basis.

The dependent claims do not correct the above described indefiniteness.

3. Claims 23, 24, 26, and 28-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims now recite limitations which were not clearly disclosed in the specification, as filed, and now change the scope of the disclosure. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112. The original specification contemplated dendritic cells which present prostate cancer antigens but did not disclose or contemplate dendritic cells which present normal prostate antigens from normal prostate tissue as now encompassed by the claim language.

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## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.
- 5. Claims 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Cohen et al. (U.S. # 5,643,786).

The claims are drawn to compositions comprising isolated human dendritic cells exposed to a prostate tissue antigen which may include LNCaP lysate or prostate tumor lysate.

Cohen et al. teach isolated human dendritic cells which have been exposed to prostate tumor lysate. See column 11, lines 28-32 and column 12, lines 22-30.

6. Claims 23 and 24 are rejected under 35 U.S.C. 102(a) as being anticipated by Tjoa et al. (The Prostate 27:63-69, 1995).

The claims are drawn to compositions comprising isolated human dendritic cells exposed to a prostate tissue antigen which may include LNCaP lysate or prostate tumor lysate.

Tjoa et al. teach compositions comprising isolated human dendritic cells exposed to LNCaP lysate (see page 64, column 2, third paragraph and page 66, last paragraph into page 67.

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### Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (U.S. # 5,643,786) or Tjoa et al. (The Prostate 27:63-69, 1995) as applied to claims 23 and 24 in view of Lutz et al. (J. Immunol. Methods 174:269-279, 1994 IDS BV).

Cohen et al. and Tjoa et al. teach as set forth above but fail to teach extended life span dendritic cells.

Lutz et al., however, teach making immortalized dendritic cells (see abstract). Lutz et al. also teach that the problem of being unable to maintain dendritic cells in vitro for long periods of time can be overcome by immortalizing them (page 278)

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute the dendritic cells of Cohen et al. or Tjoa et al. with the immortalized, extended life span, cells of Lutz et al. One or ordinary skill in the art at the time the invention was made would have been motivated to use immortalized dendritic cells to be able to maintain the cell long term in vitro.

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9. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (U.S. # 5,643,786) or Tjoa et al. (The Prostate 27:63-69, 1995) as applied to claims 23 and 24 in view of Taylor et al. (Cryobiology 27:269-278, 1990 IDS CV).

Cohen et al. and Tjoa et al. teach as set forth above but fail to teach cryopreservation of the dendritic cells.

Taylor et al., however, teach cryopreservation of dendritic cells. Taylor et al. teach that the cryopreserved dendritic cells can be used in immunological procedures.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute the dendritic cells of Cohen et al. or Tjoa et al. with the cryopreserved dendritic cells of Taylor et al. with a reasonable expectation of success and one would have been motivated to do so in order to preserve the previously isolated dendritic cells.

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (U.S. # 5,643,786) or Tjoa et al. (The Prostate 27:63-69, 1995) as applied to claims 23 and 24 in view of Taylor et al. (Cryobiology 27:269-278, 1990 IDS CV) as set forth for claims 28 and 29 further in view of Lutz et al. (J. Immunol. Methods 174:269-279, 1994 IDS BV).

Cohen et al., Tjoa et al., and Taylor et al. teach as set forth above but fail to teach extended life span dendritic cells.

Lutz et al., however, teach making immortalized dendritic cells (see abstract). Lutz et al. also teach that the problem of being unable to maintain dendritic cells in vitro for long periods of time can be overcome by immortalizing them (page 278)

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Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute the dendritic cells of Cohen et al. or Tjoa et al., as modified by Taylor with cryopreserved, immortalized, extended life span, cells of Lutz et al. with a reasonable expectation of success. One or ordinary skill in the art at the time the invention was made would have been motivated to use immortalized dendritic cells to be able to maintain the cell long term in vitro.

#### NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvonne Eyler, Ph.D. whose telephone number is (703) 308-6564. The examiner can normally be reached on Monday through Friday from 830am to 630pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paula.hutzell@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Yvonne Eyler, Ph.D. Primary Examiner

September 26, 1999